

Claims

1. (currently amended) An interlabial delivery device comprising a ~~delivery material pad~~, wherein the ~~device pad~~ is configured to be retained between labia of a subject, and the ~~device pad~~ carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent;

AI wherein the pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion and wherein the minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space.

2. (cancelled).

3. (original) The device of claim 2, wherein the pad is a highly absorbent non-swellable material.

4. (currently amended) The device of claim 2, wherein the pad ~~has a uniform cross-section along its entire length or is tapered along its length~~ is elongated to extend along the interlabial space to frictionally engage the pad against the labia and enable the pad to resist dislodgement.

5. (currently amended) The device of claim 2, wherein the pad ~~has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion and wherein the minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space~~ includes a cavity in an external surface of the pad, wherein substantially all the diagnostic or therapeutic agent is contained within the cavity.

6. (currently amended) The device of claim 5 ~~1~~, wherein the minor ~~an~~ and major portions of the pad have a an elliptical cross-section with a major axis, wherein the major axis of the minor portion is less than the major axis of the major portion, and the major axis is of a sufficient size to retain the device substantially completely external to a vaginal orifice.

7. (original) The device of claim 1, wherein the delivery material includes an agent for absorbing odors.

8. (original) The device of claim 1, wherein the agent is a diagnostic agent.

9. (original) The device of claim 1, wherein the agent is a therapeutic agent.

10. (original) The device of claim 1, wherein the delivery device comprises an intravaginal portion and an extravaginal portion, and the intravaginal portion carries the agent to be delivered.

11. (original) The device of claim 1, wherein the agent is an antibiotic or anti-fungal agent.

12. (original) The device of claim 1, wherein the agent is a hormone.

13. (original) The device of claim 1, wherein the agent is a transdermal agent.

14. (currently amended) The device of claim 1, wherein the agent is a drug ~~is in~~ a unit dosage form.

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15. (currently amended) A method of treating a disease, comprising:
positioning a device configured to be retained between labia of a subject in an interlabial space of a subject in need of ~~the a~~ therapeutic agent to treat the disease, wherein the device is a pad which carries a therapeutically ~~or diagnostically~~ effective amount of an active agent, or the agent has already been applied to the labia or ~~administered~~ administered intra-vaginally prior to placing the pad in the interlabial space; and
retaining the pad in the interlabial space to dispense or retain the therapeutic agent.

16. (currently amended) The method of claim 15, wherein the device is placed and retained substantially completely external to a vaginal orifice.

17. (original) The method of claim 15, wherein the pad has a tapered leading edge, and the method further comprises inserting the pad into an interlabial space to push the labia apart as the leading edge of the pad is inserted between the labia.

18. (currently amended) The method of claim 17, wherein the tapered leading edge is positioned against the external vaginal orifice, and a remainder of the pad has a width which is wider than a normal anatomic interlabial space, such that the remainder of the pad is frictionally engaged and retained by opposing labia.

19. (original) The method of claim 17, wherein the pad is elongated.

20. (original) The method of claim 15, wherein the method is a method of locally delivering the agent to the peri-labial area.

21. (currently amended) The method of claim 20, wherein the method is a method of systemically delivering the agent translabially.

22. (currently amended) A method for administering a drug to a subject, comprising inserting a pad impregnated with the drug into the subject's interlabial space, positioning the pad ~~adjacent to~~ against the subject's external vaginal orifice, wherein the pad is devoid of corners and flat surfaces ~~intermediate its ends~~, and the pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion, wherein both the minor and the major portion are curvilinear in cross-section, and wherein the minor portion facilitates insertion between the subject's labia and retention in the interlabial space; and
retaining the pad in the interlabial space to dispense the drug interlabially.

a 23. (original) The method of claim 22, wherein the pad is elongated and has a uniform cross-section along its entire length, or is tapered along its length.

24. (currently amended) The method of claim 22, wherein the pad is elongated, and when placed in the interlabial space to dispense the drug, extends completely external to the vaginal orifice.


25. (original) The method of claim 22, wherein the pad carries a therapeutically effective amount of a medicinal agent, and positioning the pad comprises administering the medicinal agent to the subject.

23 26. (currently amended) The method of claim 22, wherein the medicinal agent is an antifungal agent or a hormone.

24 27. (currently amended) The method of claim ~~23, wherein the hormone is estrogen or testosterone~~ 22, wherein the pad includes a recess that extends along an exterior surface of the pad, and in which the drug is placed, wherein compression of the pad compresses the recess to dispense the drug.

~~25~~ 28. (currently amended) A method for treating a symptom of a subject, comprising positioning an interlabial elongated absorbent pad such that the pad is retained between the labia external to the subject's vaginal orifice, wherein the pad comprises a longitudinally extending major portion and a longitudinally extending minor portion integrated with the posterior portion, wherein the minor portion has a smaller transverse section diameter relative to the larger transverse section diameter of the major portion, wherein the minor portion is designed for insertion of the pad between the subject's labia in the anatomic interlabial space adjacent to the vaginal opening, and the major portion is attached to the anterior portion such that is retained between the labia, wherein insertion and retention of the pad adjacent to the vaginal opening reduces the symptom; and

retaining the pad in the interlabial space.

 ~~26~~ 29. (currently amended) The method of claim ~~25~~ 22, wherein the minor and major portions of the pad have a length greater than their width, and the shape of the pad substantially conforms to the interlabial space in which the pad is retained.

~~27~~ 30. (currently amended) The method of claim ~~26~~ 29, wherein the pad is held between the labia without adhesive or attachment to a supporting garment.

~~28~~ 31. (currently amended) The method of claim ~~25~~ 22, wherein the major portion of the pad has longitudinally extending, opposed, substantially parallel face portions.

~~29~~ 32. (currently amended) The method of claim ~~25~~ 22, wherein the minor portion of the pad has longitudinally extending, opposed substantially parallel face portions.

~~30~~ 33. (currently amended) The method of claim ~~29~~ 32, wherein the opposed flat face portions of the pad are substantially parallel.

~~31~~ 34. (currently amended) The method of claim ~~29~~ 32, wherein the opposed flat face portions of the pad are substantially convergent.

~~32~~ 35. (currently amended) The method of claim ~~28~~ 31, wherein the minor portion of the pad has longitudinally extending, opposed substantially parallel face portions.

~~33~~ 36. (currently amended) The method of claim ~~32~~ 35, wherein the opposed flat face portions of the pad are substantially parallel.

~~34~~ 37. (currently amended) The method of claim ~~38~~ 36, wherein the opposed flat face portions of the pad are substantially convergent.

~~35~~ 38. (currently amended) The method of claim ~~25~~ 22, wherein the minor and major portions of the pad have a shoulder shaped junction.

~~36~~ 39. (currently amended) The method of claim ~~25~~ 22, wherein the pad carries a therapeutically effective amount of a medicinal agent, and positioning the pad comprises administering the medicinal agent to the subject to relieve the symptom.

~~37~~ 40. (currently amended) The method of claim ~~42~~ 39, wherein the medicinal agent is an anti-microbial or a hormone.

~~38~~ 41. (currently amended) The method of claim ~~25-22~~, wherein the pad includes a cavity in which a medicinal agent is placed prior to positioning the pad.

~~39~~ 42. (currently amended) The method of claim ~~38~~ 41, wherein the cavity is compressed between the labia when the pad is positioned.

~~40~~ 43. (currently amended) The method of claim ~~39~~ 42, wherein the cavity communicates with an exterior surface of the pad.

~~41~~ 44. (currently amended) The method of claim ~~40~~ 43, wherein the cavity is a recess in an exterior surface of the minor portion of the pad.

~~42~~ 45. (currently amended) The method of claim ~~41~~ 44, wherein the pad is elongated, and the cavity extends longitudinally along the pad.

~~43~~ 46. (currently amended) The method of claim ~~25~~ 28, wherein the method further comprises applying medication intravaginally or perilabially prior to or simultaneously with positioning the pad.
